PSJ10 Exh 39

Actavis | DEA Affairs
Controlled Substance Suspicious Order Monitoring: 'Order of Interest' Evaluation

PURPOSE

To define the requirements and establish guidelines for the evaluation of controlled substance orders of interest suspended by the Suspicious Order Monitoring System (SOMS) and report controlled substance suspicious orders to the Drug Enforcement Administration (DEA).

SCOPE

This policy applies to all Actavis facilities registered with the Drug Enforcement Administration (DEA) to handle controlled substance products.

DEFINITIONS

Order of Interest: An order "pended" within the SOMS that is deemed "of interest" until it is investigated. Pended orders that are determined to be releasable must be approved by a member of DEA Affairs.

Pend: Orders which have been blocked or stopped in real time by the SOMS because they exceeded the calculations and business rules established by Actavis.

Suspicious Orders: Controlled substance orders which are of unusual size, deviate substantially from a normal pattern or are of unusual frequency and List I chemical orders which may involve extraordinary quantity uncommon method of payment or deliver or any other suspicious circumstance.

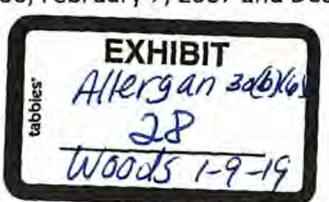
21 CFR 1301.74(b) states that "the registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

21CFR 1310.05 (a) (1) states that "Each regulated person shall report to the Special Agent in Charge of the DEA Divisional Office for the area in which the regulated person making the report is located, as follows:

(1) Any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of this part."

RELATED DOCUMENTS

Title 21, Code of Federal Regulations, Section 1301.74(b)
Letters from the Drug Enforcement Administration dated September 27, 2006, February 7, 2007 and December 27, 2007



PROCEDURE

1.0 Pended Orders

1.1 Orders for all Actavis customers are individually analyzed via an internal computerized statistical calculation to determine whether the order may be of unusual size, whether the order may deviate substantially from a normal pattern and/or whether the order can be associated with an unusual pattern or frequency. The statistical analysis is accomplished by a formula that uses a statistical algorithm and compares current orders from previous orders. This analysis will assign a "score" to each order based upon the analysis. This score will help to identify the level of suspicion of a pended order. An order will "pend" if any or all of these attributes are present to a statistically extent. These orders may be suspicious and must be investigated before shipping to the customer.

1.2 Customer orders with no previous history (new customer, new NDC, 1st time purchase of a GDC) will "pend" until there are purchases in two distinct months within the last six months. At that point it becomes part of the mathematical calculations of the model.

1.3 All "pended" orders will then be initially reviewed by the Customer Service department. The specific order information is presented on a series of (order/inventory system) review screens.

2.0 Order of Interest Evaluation

2.1 All orders will be "pended" in real time and the entire controlled substance order will "pend" until investigated and either cleared of suspicion or reported to DEA.

2.2 All orders will be initially investigated by the Customer Service Master Data Administrator.

2.3 The Master Data Administrator will gather relevant information to begin the review process. The following information will initially be considered:

- **A.** The customer's order history with this drug.
- **B.** Any "notes" in the customer file pertaining to the drug that has been "pended."
- **C.** Whether other orders for this account have been "pended" before and what actions were taken on these pended orders.

2.4 After organizing this information, the Master Data Administrator will telephone or e-mail the customer. The Master Data Administrator will advise the customer *in general terms* of why the order pended.

2.5 The Master Data Administrator forwards all documentation to DEA Affairs personnel for review and evaluation. Orders are not released until approval is granted by DEA Affairs personnel.

2.6 Some of the reasons that might allow DEA Affairs personnel to clear an order of interest include:

- Order error
- New and/or type of customers (requires confirmation)
- Verified increased market growth
- Market shortage
- New or different drug
- Different size or preparation
- Results of on-site review

2.7 If the order cannot be cleared based on the documentation provided by Customer Service personnel or if the customer has had previous orders pended and provided similar reasons, the reasons will be further investigated.

2.7.1 DEA Affairs and Customer Service management may host a "Customer Partnership" teleconference with the customer to initiate further discussion and gain additional information.

2.7.2 The DEA Affairs Compliance Auditor/Investigator may conduct an on-site visit to identify and examine the facility. Information to be considered may include buying groups, pharmacies, clinics, medical facilities and/or physicians. The on-site visit will seek to document any development that would legitimately cause an increase in the account's use of controlled substances. The results of the on-site investigation will be documented and the results of the investigation will be forwarded to DEA Affairs management for final review.

2.8 If DEA Affairs personnel determine that there is sufficient evidence in the file to conclude that the order is legitimate the entire controlled substance order will be cleared as an order of interest and released.

3.0 Reporting a Suspicious Order to the DEA

3.1 If an order cannot be cleared of suspicion, the DEA Affairs management will notify the local DEA Field Office in the area where the order has been placed, via telephone and then in writing via facsimile, that there is a suspicious order.

3.2 The order will be cancelled in its entirety and the account will be re-examined for possible closure.

3.3 Any conversations with any DEA personnel will be documented to include the name and title of the DEA employee and a summary of what was discussed.

4.0 Internal Audit Program

4.1 All orders that have been "pended" and "cleared" will be incorporated into Actavis's internal audit program.

